

# Notice of Allowability

Application No.

10/066,551

Examiner

Padmavathi v. Baskar

Applicant(s)

APICELLA ET AL.

Art Unit

1645

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/25/06.
2. ☒ The allowed claim(s) is/are 1, 7, 21, 24, 25, 61, 63, 64, 65, 66, 67, 68, 62, 23, 71-74 and have been renumbered as 1-18 respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 10/5/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 12/4/06
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants submission filed on 9/25/06 has been entered. MPEP 7.42.04

#### ***Status of Claims***

2. Claims 21, 23-25 and 61-64 have been amended,  
Claims 15 and 60 are canceled.  
Claims 69-74 have been added.  
Claims 1, 7, 21, 23-25, and 61-74 are currently pending.

#### ***Examiner's amendment***

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Apicella Michael and Ann Viksnins on 12/4//06 (see attached interview summary). The application has been amended as follows:

Claim 1. (Currently Amended) A purified or isolated secreted protein comprising a 55 kD polypeptide from *Neisseria gonorrhoeae* , wherein the molecular weight of the 55 kD polypeptide is determined by electrophoresis of gonococci supernatant filtrate suspended in 1 M Tris - 1% SDS in a sodium dodecyl sulfate 12 % to 4% polyacrylamide gradient gel under

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reducing conditions, wherein the protein is involved in modification of cell membrane enhancing bacterial entry.

Claims 69 and 70 are canceled

***Claim rejection 35 USC 112, first paragraph withdrawn***

4. In view of amendment to the claims 15, 21, 23-25 and 60-64 (vaccine composition), the rejection under 35 U.S.C. 112, first paragraph is withdrawn.

***Conclusion***

5. 1, 7, 21, 24, 25, 61, 63, 64, 65, 66, 67, 68, 62, 23, 71-74 are allowed and have been renumbered as 1-18 respectively.

6. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

  
Padma Baskar Ph.D.

**CLEAN COPY OF ALLOWED CLAIMS**

Claim 1. A purified or isolated secreted protein comprising a 55 kD polypeptide from *Neisseria gonorrhoeae*, wherein the molecular weight of the 55 kD polypeptide is determined by electrophoresis of gonococci supernatant filtrate suspended in 1 M Tris - 1% SDS in a sodium dodecyl sulfate 12 % to 4% polyacrylamide gradient gel under reducing conditions, wherein the protein is involved in modification of cell membrane enhancing bacterial entry.

Claim <sup>2</sup>~~7~~. A purified or isolated protein comprising the amino acid sequence of SEQ ID NO:4.

Claim <sup>3</sup>~~2~~<sup>1</sup>. The purified or isolated protein of claim 1, wherein the protein is expressed from an isolated nucleic sequence encoding the protein.

Claim <sup>4</sup>~~2~~<sup>4</sup>. The purified or isolated protein of claim 1, wherein the protein is conjugated or linked to a second peptide.

Claim <sup>5</sup>~~2~~<sup>5</sup>. The purified or isolated protein of claim 1, wherein the polypeptide is conjugated or linked to a polysaccharide.

Claim <sup>6</sup>~~6~~<sup>1</sup>. The purified or isolated protein of claim <sup>2</sup>~~7~~, wherein the protein is expressed from an isolated nucleic sequence encoding the protein

Claim <sup>7</sup>~~6~~<sup>3</sup>. The purified or isolated protein of claim <sup>2</sup>~~7~~, wherein the protein is conjugated or linked to a second peptide.

Claim <sup>8</sup>~~6~~<sup>4</sup>. The purified or isolated protein of claim <sup>2</sup>~~7~~, wherein the protein is conjugated or linked to a polysaccharide.

Claim <sup>9</sup>~~6~~<sup>5</sup>. A composition prepared by combining the purified or isolated protein of claim 1 with a carrier.

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Claim <sup>10</sup>~~66~~. A composition prepared by combining the purified or isolated protein of claim <sup>2</sup>~~7~~ with a carrier.

Claim <sup>11</sup>~~67~~. A composition comprising the purified or isolated protein of claim 1 in combination with a physiologically acceptable, non-toxic vehicle.

Claim <sup>12</sup>~~68~~. A composition comprising the purified or isolated protein of claim <sup>2</sup>~~7~~ in combination with a physiologically acceptable, non-toxic vehicle.

Claim <sup>13</sup>~~62~~. The composition of claim <sup>12</sup>~~68~~, which further comprises an effective amount of an immunological adjuvant.

Claim <sup>14</sup>~~28~~. The composition of claim <sup>11</sup>~~67~~ which further comprises an effective of an immunological adjuvant.

Claim <sup>15</sup>~~71~~. A composition comprising the isolated or purified protein of claim <sup>4</sup>~~24~~ combination with a physiologically acceptable, non-toxic vehicle.

Claim <sup>16</sup>~~72~~. A composition comprising the isolated or purified protein of claim <sup>7</sup>~~68~~ in combination with a physiologically acceptable, non-toxic vehicle.

Claim <sup>17</sup>~~73~~. A composition comprising the isolated or purified protein of claim <sup>5</sup>~~26~~ in combination with a physiologically acceptable, non-toxic vehicle.

Claim <sup>18</sup>~~74~~. A composition comprising the isolated or purified protein of claim <sup>8</sup>~~64~~ in combination with a physiologically acceptable, non-toxic vehicle.